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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,344	09/10/2004	Lauretta Maggi	28069-602 NATL	3801

7590

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EXAMINER

HAWES, PILI ASABI

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/507,344	Applicant(s) MAGGI ET AL.	
	Examiner Pili A. Hawes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of the Remarks and Amendments filed 12-22-2005 is acknowledged.

Claims 1-27 are pending in this action. Claims 1-27 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 8-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte US 5487901.

Conte discloses a pharmaceutical tablet composed of an upper layer containing active ingredient, formulated for immediate release, an intermediate layer that does not contain any active agents and is formulated with polymers as a semipermeable membrane, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being almost completely coated with an insoluble polymeric coating (col. 2, lines 30-45). The tablets is completely coated with an

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impermeable polymeric film (col. 2, lines 52-53). The upper layer also comprises polymeric excipients (col. 4, lines 1-9). The amount of the excipient with respect to the total weight of the tablet is 1-90% by wt (col. 4, lines 10-13). The upper layer is 0.5-5 mm thick (col. 4, line 39). The intermediate layer is made of gelable or erodible polymers (col. 4, lines 40-53). The amount of polymeric substance in respect of the total weight of the tablet is 5-90% (col. 4, lines 55). The intermediate layer is 0.1-4.5 mm thick (col. 5, lines 31). The third layer has the same composition as the upper layer (col. 5, lines 32-36). The lower layer is 0.5-5 mm thick (col. 5, line 37). The tablet is coated with an impermeable polymeric material that is insoluble or exhibits delayed solubility, or a solubility that is pH dependent (col. 5, lines 40-46). The polymeric coating in respect of the finished tablet is 0.2-20% by wt (col. 5, lines 54-55). The upper layer is partially exposed to the environmental fluid because a raised portion was removed after final coating with impermeable polymeric coating (col. 2, lines 54-55). The reference discloses that the removal of the raised portion may be carried out by techniques already available on the market (col. 5, lines 61-64). This teaching does not rule out using laser to remove the raised portion. In any case, as was stated above in the previous rejection, claim 1 is a product by process claim. The process by which a product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product of the prior art. In this case the prior art clearly anticipates the instant claimed product, and therefore the process limitation of using a laser to incise the impermeable polymeric

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membrane in the product claims does not impart patentable weight. The burden is upon applicant to show that instant product is patentably distinct from Ayer's product.

Claims 1, 2, 4, 5, 8-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Conte et al. US 5650169.

Conte '169 is a divisional of Conte '901. The disclosures are identical and the disclosure of '169 discloses all of the limitations discussed in the previous rejection. See above.

Response to Arguments

Applicants argue that Conte does not teach an external coating that is impermeable and insoluble that coats the entire tablet.

Conte clearly teaches using an impermeable coating (col. 2, lines 51-52).

b) coating the tablet as per step a) entirely with an impermeable polymeric film;

Conte also teaches that the impermeable polymer is insoluble (col. 2, lines 44-45).

an impermeable polymeric film, consisting of a polymer either insoluble or exhibiting a delayed solubility

It is clearly a contemplated embodiment of the Conte's invention to coat the tablet with an impermeable and insoluble polymer coating. The fact that the tablets are not completely coated further anticipates Applicants claims because Applicants themselves claim a portion of the coating is incised exposing layers of the tablet. Thus the tablet of Applicants invention could not be entirely coated.

Claims 1, 3, 6-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Faour US 6599284 B2.

Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredient (2), an intermediate layer forming a

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semipermeable membrane (3), and an inner layer or core containing active ingredient (4) (Figure 4). The dosage form also comprises a passageway (5) formed by laser incision (col. 13, lines 48-55), which is incised in correspondence with both the first and third layer (Figure 4). The reference also teaches the addition of osmopolymers (col. 16, lines 1-45), and disintegrating agents (col. 18, lines 25-38). The reference further discloses that the outer layer or external coating layer may contain the same or different active ingredients as the inner layer (col. 13, lines 5-7). Example 1 discloses the composition of the inner core, which comprises more than 49% by wt polymeric material (col. 24, lines 15-25). Example 1 also discloses the use 5% by wt of polyethylene glycol (col. 24, lines 25-30). Faour incorporated by reference Theeuwes et al. US 4088864, which discloses the laser source as CO₂ and the output of 20W. Therefore the process claims are also anticipated by this reference.

Response to Arguments

Applicant argues that Faour does not teach an impermeable external coating.

It is a contemplated embodiment of Faour to select an insoluble coating for the external layer. See columns 12 and 13 of Faour reproduced below:

^{rv} The external coat is comprised of one or more coatings, which are generally independently selected at each occur-

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rence from the group consisting of: a drug-containing coating, a release rate modifying coating, a porous coating; a soluble coating, an insoluble coating, a semipermeable membrane; and a delayed release coating.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

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